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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,624	07/30/2001	Xiao Min Schebye	PA-0033 US	3179
27904	7590	12/04/2003	EXAMINER	
INCYTE CORPORATION (formerly known as Incyte Genomics, Inc.) 3160 PORTER DRIVE PALO ALTO, CA 94304			CHAKRABARTI, ARUN K	
		ART UNIT	PAPER NUMBER	
		1634		

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/918,624</b>	Applicant(s) <b>SCHEBYE</b>
	Examiner <b>Arun Chakrabarti</b>	Art Unit <b>1634</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on Oct 14, 2003
  - 2a)  This action is FINAL.      2b)  This action is non-final.
  - 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4)  Claim(s) 1-19 is/are pending in the application.
  - 4a) Of the above, claim(s) 6-10 and 15-19 is/are withdrawn from consideration.
  - 5)  Claim(s) \_\_\_\_\_ is/are allowed.
  - 6)  Claim(s) 1-5 and 11-14 is/are rejected.
  - 7)  Claim(s) \_\_\_\_\_ is/are objected to.
  - 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some\* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
  - a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1003
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: *Detailed Action*

Art Unit: 1634

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group I and ten elected sequences 1-3, 6, 8-11, 20 and 22 in Paper No. 1003 is acknowledged. The traversal is on the ground(s) that the examination of claims 1-5 and 11-14 with respect to ten elected sequences would pose no undue burden. Argument regarding examination of claims 1-5 and 11-14 has been found persuasive and therefore are hereby being examined but argument regarding ten elected sequences has not been found persuasive because search of SEQ ID NO: 2 pose real burden as it has 10,211 residues, which is longer than the limit of patent office's capability of searching 10,000 residues per sequence. Moreover, searching of remaining 9 SEQ IDs 1, 3, 6, 8-11, 20 and 22 requires 35+ hours of processing time which is over the limit of patent office's capability of searching for 23 hours per application. This is *prima facie* evidence of burdensome search. However, three SEQ IDs 1, 3, and 8 have been searched.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 12, line 31. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Art Unit: 1634

***35 U.S.C. 101/112 Utility Rejections***

3. 35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 11-14 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed use(s) of the nucleic acids are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds may be useful as probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed.

Further, the claimed nucleic acid and/or protein compound(s) is(are) not supported by a substantial utility because no substantial utility has been established for the claimed subject matter.

Art Unit: 1634

For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds.

Claim(s) 1-5 and 11-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1634

4. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 are rejected over the recitation of the phrases, "differential expression of the cDNAs is greater than 2.5" and "differential expression of the cDNAs is greater than 3.0" respectively. It is not clear how the numbers 2.5 and 3.0 are derived, what are the units of expression and if it is a ratio, what is the standard compared to which these numbers have been calculated. In absence of any definition of numerical differential expression of the cDNAs or the standard of comparison in the claim, it is not clear what is claimed. The metes and bounds of the claims are vague and indefinite.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Turner et al.

(Blood (1991), Vol. 78 (Suppl. 1), page 279).

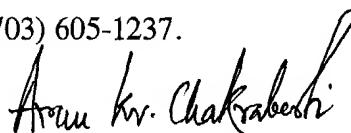
This rejection is based on the fact that, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the

Art Unit: 1634

prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, a cDNA having SEQ ID NO: 1 has been clearly taught by Turner et al. (Gen bank Accession Number U70136; bases 1 to 5041). The intended use of the present claim i.e., differential expression during adipocyte differentiation is not given any patentable weight because SEQ ID NO: 1, as taught by Turner et al., inherently possesses the same claimed function as it is structurally identical.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.



Arun Chakrabarti,  
**ARUNK. CHAKRABARTI**  
**PATENT EXAMINER**

Patent Examiner,

October 13, 2003



**GARY BENZION, PH.D.**  
**SUPERVISORY PATENT EXAMINER**  
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